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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/480,432	01/11/2000	RICHARD S. SURWIT	9025-7	4307

20792 7590 10/03/2003

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EXAMINER	
BLECK, CAROLYN M	

ART UNIT	PAPER NUMBER
3626	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/480,432	SURWIT ET AL.	
	Examiner	Art Unit	
	Carolyn M Bleck	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Notice to Applicant

1. In view of the appeal brief filed on 15 July 2003, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

2. Claims 1-43 are pending. After re-considering Applicant's Appeal brief filed 15 July 2003 and the previous Office Action mailed 7 March 2003, the finality of that action is withdrawn. The Examiner made some inadvertent mistakes concerning the rejection of claims, in particular with respect to groupings of claims under 35 U.S.C. § 103(a). In particular, within the Final Rejection mailed 7 March 2003 (Paper No. 10), the Examiner inadvertently lumped the rejections of claims 29, 33-37, and 41-42 together with that of 1, 5-7, 9-10, 14-16, and 18, as one grounds of rejection; however, these two groupings of claims were rejected on different grounds in the previous Action mailed 3 October

2002 (Paper No. 8). As a result, the Examiner is issuing the present Office Action to make the record more clear and complete.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 5-7, 9-10, 14-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095) and the Applicant's admission in the background of the invention of the present application (09/480432).

(A) As per claim 1, Walker discloses:

(a) receiving data from a patient at a patient telemetry device, wherein an input/output circuit forms an interface between the patient telemetry device and sources of physiological data, wherein the patient data includes at least one of physiological data or parameter such as heart rate, blood pressure, temperature, perspiration level, respiratory activity, body electrical activity, and brain activity (reads on "neuropsychological data") (Fig. 1, 11-12, col. 3 lines 9-16 and 58-62, and col. 4 lines 60-67);

(b) performing an analysis by the processor of the telemetry device to determine if monitored parameters are within appropriate boundaries, wherein an alert is issued by the telemetry device in the event of a patient heart rate exceeding an upper threshold level or dropping below a threshold level, wherein multiple parameter alarms may be programmed such that particular combinations of physical parameter levels trigger specific alerts indicative of specific conditions (Fig. 1, col. 5 line 58 to col. 6 line 15, col. 8 lines 5-17, and col. 19 lines 20-31);

(c) if monitored parameters are not within appropriate boundaries, the telemetry device decides locally to dispense drugs in the case of a patient exhibiting physiological information indicative of cardiac arrest, wherein the medication reduces or mitigates any harm to the patient due to the event,

or

instructing the patient to take insulin, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (Although Walker does not specifically recite "prompting a patient to perform a test," it is noted that the telemetry device of Walker is performing analysis locally, and is thus either dispensing a drug or instructing a patient to perform an action in response to the analysis which are both forms of "prompting" the patient. Furthermore it is well known in the art that a telemetry device such as Walker's which is monitoring blood glucose levels and is able to find that a patient requires insulin, and then "alerts a nurse or physician if the levels do not return to normal after a predetermined period of time", would also require a patient telemetry

device to locally perform a second blood glucose "test" to determine that the levels have not returned to normal) (col. 6 lines 16-33, col. 8 lines 5-40, col. 19 lines 20-31, col. 20 lines 26-55);

(d) receiving data at the patient telemetry device (col. 3 lines 7-22), wherein the data includes dispensed medications (col. 6 lines 16-33); and

(e) communicating the physiological representative data including results and levels from the patient telemetry device to an expert, such as a physician or nurse, via the internet, telecommunications network, microwave link, satellite link, wireless communication medium (col. 4 lines 32-49, col. 8 lines 5-40, col. 20 lines 26-55, col. 22 lines 50-67, and col. 26 lines 55-60).

Walker fails to expressly disclose a portable apparatus (emphasis added). Brown includes a method to encourage and monitor compliance with a treatment regimen (col. 3 lines 63-67), wherein a portable device is coupled to a communication system with feedback to monitor patient compliance with and effectiveness of treatment regimens, wherein input from patients regarding treatment regimens can be recorded, reviewed, and analyzed, wherein treatment regimens in response to feedback from patient can be altered, wherein the medication regimen includes obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill, a physical therapy regimen including exercising, stretching, changing position, or changing work routine, and a psychological regimen including repeating an affirmation, meditation, self-hypnosis or other mental activity, or a

self-help regimen such as weight loss including drinking water or eating a snack (Fig. 1-2, col. 1 line 57 to col. 2 line 67, col. 3 lines 1-17, col. 5 lines 3-23, and col. 6 line 55 to col. 8 line 31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components, specifically the portability of the patient apparatus, of Brown within the method of Walker with the motivation of ensuring patients are restricted as little as possible regarding their activities and movements (Brown; col. 1 lines 57-60), encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26).

Although Walker includes instructing a patient to perform an action as discussed above, Walker and Brown fail to expressly disclose monitoring anticoagulation therapy using a specific medication regimen and coagulation test. In the background of the invention of the present application, it is disclosed that anticoagulation therapies include warfarin and other vitamin K antagonists, heparin and similar glucosaminoglycans, and direct thrombin inhibitors (e.g., hirutin, melagatgran) and the tests include prothrombin (PT), partial thromboplastin time (PTT), activated clotting time (ACT), specific heparin or low molecular weight heparin assays, ecarin clotting time (ECT), thrombin clotting time, and PT or PTT (pg. 6). Further, Applicant discloses in the background of the invention

that home monitoring devices have been developed and marketed to collect physiologic data and report the data to a physician, wherein the devices include home coagulation time monitors for patients undergoing anticoagulation therapy (pg. 4). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include monitoring the aforementioned therapies and tests disclosed in the background of the invention within the method taught collectively by Walker and Brown with the motivation of increasing patient compliance with complex treatment regimens and reducing the number of potential side effects by allowing for remote monitoring of treatment regimens (Walker; col. 1 lines 10-64, col. 2 lines 8-27, and col. 3 lines 9-26).

In addition, insofar as Applicant recites "selected from the group consisting of..." and "at least one of...", it is irrelevant whether or not Walker or Brown disclose every single statement recited in the claim.

(B) As per claim 5, Brown discloses receiving from the patient device, information about patient compliance with the treatment regimen including medication taken by the patient, physical therapy regimen, psychological therapy, self-help regimen, and tests during a time interval dictated by the treatment regimen (col. 2 lines 1-13, col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 37 to col. 8 line 31). The remainder of claim 5 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein. The motivation for combining Brown with Walker is given above in claim 1, and incorporated herein.

(C) As per claim 6, Walker discloses receiving data from a patient telemetry device at a central server (col. 8 lines 5-40 and col. 20 lines 26-55) and then transmitting a copy of at least a portion of the patient's medical history and a description of the current pattern or data aberration to the medical expert via a network if at least one physiological data or parameter is not within appropriate or "normal" parameter boundaries (Fig. 11-12, col. 1 line 65 to col. 2 line 67, col. 3 line 55 to col. 4 line 48, col. 5 line 57 to col. 6 line 15, col. 7 lines 12-63). The remainder of claim 6 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given above for claim 1, and incorporated herein.

(D) As per claim 7, Walker discloses transmitting information to the physician via a pager or personal digital assistant (PDA) (col. 4 lines 32-48).

(E) As per claim 9, Walker, Brown, and the background of the invention fail to expressly disclose the received patient data including at least one of information about hemorrhagic symptoms experienced by the patient and information about a non-hemorrhagic symptoms experienced by the patient. However, Brown discloses sending information to the central server, wherein the information sent is related to compliance with a medication regimen including obtaining medicine, taking the medicine, taking the medicine with another substance such as food or water, not taking the medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill (col. 5 lines 8-23 and col. 6 line 55 to col. 8 line 31). It is respectfully

submitted that when informing a physician of compliance with a medication regimen, a physician would typically desire to know if a patient had experienced any symptoms, including those related to hemorrhagic or non-hemorrhagic symptoms. At the time the invention was made, the skilled artisan would have found it an obvious modification to have included information related to symptoms such as hemorrhagic or non-hemorrhagic symptoms with the motivation of determining whether treatment regimens are having the desired and intended effects, are effective, or whether patients are suffering any untoward side effects, and monitoring and recording whether non-prescribed treatment regimens, such as by undertaking medication, are producing intended results (Brown; col. 2 lines 1-13). The remainder of claim 9 repeats the same limitations of claim 1, and is therefore rejected for the same reasons given for claim 1, and incorporated herein.

(F) Claims 10, 14-16, and 18 differ from method claims 1, 5-7, and 9, discussed above, by reciting hardware elements, namely, a processor, a user interface in communication with the processor, and computer code executable by the processor. As per these elements, Walker teaches:

(a) a processor (Fig. 1-2 and col. 7 lines 12-43);

(b) a LCD display device including a data entry device to receive and transmit information in communication with a processor (Fig. 1-2 and col. 5 lines 25-44); and

(c) programs run by the processor (col. 7 lines 12-43).

The remainder of apparatus claims 10, 14-16, and 18 repeat the same limitations of method claims 1, 5-7, and 9, and are therefore rejected for the same reasons given above for claims 1, 5-7, and 9, and incorporated herein.

5. Claims 2-4, 8, 11-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844), Brown (6,161,095), and the Applicant's admission in the background of the invention of the present application (09/480432) as applied to claims 1 and 10, and further in view of Worthington et al. (6,379,301).

(A) As per claim 2, the relevant teachings of Walker, Brown, and the Applicant's background of the invention, and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Brown discloses modifying the treatment regimen used by a patient and sends the treatment regiment to the patient device using a communication network (col. 7 lines 49-62). However, Walker, Brown, and the Applicant's background of the invention fail to expressly disclose the steps of assessing severity of the received coagulation test results from the patient-administered coagulation test via the portable apparatus, and modifying the patient-administered medication regimen via the portable apparatus if the received coagulation test results from the patient administered coagulation test are assessed to be above a threshold severity level.

Worthington includes a patient-operated apparatus for measuring a blood sample of the patient, and for producing from a measurement of the blood a value, wherein a

target range is determined, and wherein if the blood value falls outside of the range when performing the test, corrective action is determined by the processor of the apparatus, and the corrective action is recommended to the patient via the apparatus (col. 4 lines 1-60).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned components of Worthington within the method taught collectively by Walker, Brown, and the Applicant's background of the invention with the motivation of allowing a patient to make a timely correction when blood tests lie outside of a range (Worthington; col. 3 lines 54-64).

(B) As per claims 3-4, Worthington discloses a healthcare provider computer in communication with the apparatus for receiving from the apparatus values and corrective actions (col. 4 lines 48-60). The remainder of claims 3-4 repeats the same limitations of claim 2, and are therefore rejected for the same reasons given above for claim 2, and incorporated herein. The motivation for combining Worthington within Walker, Brown, and the Applicant's background of the invention is given above in claim 2, and incorporated herein.

(D) As per claim 8, Brown discloses sending information including the supply and use of pharmaceuticals and medication dosage to the patient device in response to reviewing and evaluating that the patient did not comply with the treatment regimen in the time interval dictated by the treatment regimen (col. 5 lines 8-23, col. 5 line 48 to col.

6 line 14, and col. 7 line 49 to col. 8 line 31). The remainder of claim 8 repeats the same limitations of claim 2, and is therefore rejected for the same reasons given above for claim 2, and incorporated herein.

(E) Claims 11-13 and 17 repeat the same limitations as claims 2-4 and 8, discussed above, and are therefore rejected for the same reasons given above for claims 2-4, and incorporated herein.

6. Claims 19-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095), the Applicant's admission in the background of the invention of the present application (09/480432), and Surwit et al. (6,024,699)

(A) As per claims 19 and 26, Walker discloses a system for analyzing and monitoring data from remote monitoring equipment, such as patient telemetry devices, wherein the disease or physiological parameters relate to at least one of heart rate, high blood pressure, brain waves, ECG data, ventricular fibrillation, loss of consciousness, aberrant blood glucose levels, fetal heart monitor alarm, tachycardia (Fig. 3, col. 1 lines 10-64, and col. 2 lines 18-27), wherein the disease therapy such as for a cardiac patient includes a patient taking a medication and a patient using a patient telemetry device to test and monitor the patient's heart for aberrant data patterns requiring the patient to take a medication (col. 6 lines 16-33 and col. 20 lines 26-55), wherein an apparatus is

able to receive and analyze data from a patient telemetry device (col. 1 line 51 to col. 2 line 27), and wherein the system comprises:

(a) a patient telemetry device comprising:

(i) a processor (Fig. 1 and col. 4 line 49 to col. 5 line 2);

(ii) an input/output circuit interfacing with the patient telemetry device and sources of physiological data and keypad for input (Fig. 1 and col. 4 line 49 to col. 5 line 25); and

(iii) software executable by the processor for:

- measuring and storing in memory physiological parameters associated with a patient including physiological data or parameters such as heart rate, blood pressure, temperature, perspiration level, respiratory activity, body electrical activity, and brain activity (reads on "neuropsychological data") (Fig. 1, 11-12, col. 3 lines 9-16 and 58-62, and col. 4 line 49 to col. 5 line 25);
- determining if at least one physiological data or parameter is within appropriate or "normal" parameter boundaries, wherein if the data is not within the appropriate boundary, a central server determines if an event or medical anomaly (e.g. cardiac arrest or other condition) may be occurring, wherein a data profile or template exists for comparing against raw patient data to produce a level of affinity between the profile and data, and wherein a high level of affinity indicates that the data may conform to a medical anomaly or event (Fig. 11-12, col. 1

line 65 to col. 2 line 67, col. 3 line 55 to col. 4 line 33, and col. 5 line 58 to col. 6 line 15);

- instructing the patient to take medication if the received results are not within an appropriate boundary, wherein if levels, for example blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (col. 8 lines 5-40 and col. 20 lines 26-55);
- measuring and storing receiving results from a patient (col. 8 lines 5-40 and col. 20 lines 26-55); and
- communicating the physiological representative data including results and levels from the patient telemetry device to an expert, such as a physician or nurse, via the internet, telecommunications network, microwave link, satellite link, wireless communication medium (col. 4 lines 32-49, col. 8 lines 5-40, col. 20 lines 26-55, col. 22 lines 50-67, and col. 26 lines 55-60); and

(b) a central server for examining communicated data from the patient telemetry device (Fig. 1 and col. 4 lines 23-32) comprising:

(i) programs run by the processor (col. 7 lines 12-43) that:

- communicating bi-directionally patient physiological data between the patient apparatus and central server (Fig. 1, col. 4 lines 7-32 and 49 to col. 6 line 25, and col. 6 lines 3-15); and

- analyzing patient data to determine if any predefined patterns or data aberrations exist, and determining whether the patterns or aberrations are pathological, and if pathological determining appropriate treatment for the patient (col. 7 lines 44-63).

Walker fails to expressly disclose a portable patient apparatus having a user interface in communication with the processor.

Brown discloses a portable patient device including a presentation element, wherein the presentation element is human-readable visual display using LCD's, LED's or other suitable devices (reads on "interface"), wherein a portable device is coupled to a communication system with feedback to monitor patient compliance with and effectiveness of treatment regimens, wherein input from patients regarding treatment regimens can be recorded, reviewed, and analyzed, wherein treatment regimens in response to feedback from patient can be altered, wherein the medication regimen includes obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill, a physical therapy regimen including exercising, stretching, changing position, or changing work routine, and a psychological regimen including repeating an affirmation, meditation, self-hypnosis or other mental activity, or a self-help regimen such as weight loss including drinking water or eating a snack (Fig. 1-2, col. 1 line 57 to col. 2 line 67, col. 3 lines 1-17, col. 5 lines 3-23, and col. 6 line 55 to col. 8 line 31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components, specifically the portability of the patient apparatus, of Brown within the method of Walker with the motivation of ensuring patients are restricted as little as possible regarding their activities and movements (Brown; col. 1 lines 57-60), encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26), and allowing a patient to view compliance and feedback information (Brown; col. 2 lines 31-50).

Walker and Brown fail to expressly disclose monitoring anticoagulation therapy using a specific medication regimen and coagulation test. In the background of the invention of the present application, it is disclosed that anticoagulation therapies include warfarin and other vitamin K antagonists, heparin and similar glucosaminoglycans, and direct thrombin inhibitors (e.g., hirutin, melagatgran) and the tests include prothrombin (PT), partial thromboplastin time (PTT), activated clotting time (ACT), specific heparin or low molecular weight heparin assays, ecarin clotting time (ECT), thrombin clotting time, and PT or PTT (pg. 6). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include monitoring the aforementioned therapies and tests disclosed in the background of the invention within the method taught collectively by Walker and Brown with the motivation of increasing patient compliance

with complex treatment regimens and reducing the number of potential side effects by allowing for remote monitoring of treatment regimens (Walker; col. 1 lines 10-64, col. 2 lines 8-27, and col. 3 lines 9-26).

Walker, Brown, and the Applicant's background of the invention fail to expressly disclose displaying identified patient medical conditions for a patient in selectable, prioritized order according to medical severity via a remotely located client in communication with the data processing system. Surwit discloses displaying the identified patient medical conditions for each respective patient in selectable, prioritized order according to medical severity, and in response to selecting one of the identified medical conditions for a respective patient, displaying treatment options for treating the selected medical condition (Fig. 3 and col. 22 lines 1-6). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Surwit within the system taught collectively by Walker, Brown, and Applicant's background of the invention with the motivation of ensuring patients with serious medical conditions such as a patient with cardiac arrest is treated in an appropriate time frame (Walker; col. 20 lines 26-55) thus improving patient care.

In addition, insofar as Applicant recites "selected from the group consisting of..." and "at least one of...", it is irrelevant whether or not Walker or Brown disclose every single statement recited in the claim.

(B) As per claim 20, Walker discloses a system wherein the patient telemetry device with software executable by the processor for:

instructing the patient to take medication such as insulin if the received results are not within an appropriate boundary (reads on "threshold severity level"), wherein if levels such as blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (col. 8 lines 5-40 and col. 20 lines 26-55).

Walker fails to expressly disclose software executable by the processor for modifying the patient-administered medication regimen and communicating the modified patient-administered medication regimen to the patient. Brown discloses modifying the treatment regimen used by a patient and sends the treatment regiment to the patient device using a communication network (col. 7 lines 49-62).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Brown within the system of Walker with the motivation of encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted (Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26). The remainder of claim 20 repeats the same limitations of claim 19, and is therefore rejected for the same reasons given above for claim 19, and incorporated herein.

(C) As per claim 21, Brown discloses sending from the server device to the patient device updated treatment information (col. 7 lines 52-62). The remainder of claim 20 repeats the same limitations of claims 19, and is therefore rejected for the same reasons given for claim 19, and incorporated herein. The motivation for combining Brown with Walker is given above in claims 19 and 20, and incorporated herein.

(D) As per claim 22, Brown discloses communicating via cellular telephone, page, personal notebook computer, hand-held computing device, internet appliance, and personal digital assistant (col. 6 lines 37-43). The remainder of claim 22 repeats the same limitations of claims 19, and is therefore rejected for the same reasons given for claim 19, and incorporated herein. The motivation for combining Brown with Walker is given above in claims 19 and 20, and incorporated herein.

(E) As per claim 23, Surwit discloses modifying a medication dosage algorithm within a patient monitoring system (col. 23 lines 7-12). The remainder of claim 23 repeats the same limitations of claims 19, and is therefore rejected for the same reasons given for claim 19, and incorporated herein. The motivation for combining Surwit with Walker is given above in claim 19, and incorporated herein.

(F) As per claim 24, Walker discloses a central server for examining communicated data from the patient telemetry device (Fig. 1 and col. 4 lines 23-32) comprising:

(i) programs run by the processor (col. 7 lines 12-43) that:

- analyzing data continuously transmitted from the patient telemetry device at the central server to determine whether an ambulance should be summoned (col. 7 lines 12-63, col. 8 lines 6-39, and col. 20 lines 26-55); and
- sending a signal to the patient telemetry device to apprise the patient of the situation where an ambulance is being summoned (col. 7 lines 12-63, col. 8 lines 6-39, and col. 20 lines 26-55).

The remainder of claim 24 repeats the same limitations of claims 19, and is therefore rejected for the same reasons given for claim 19, and incorporated herein.

(G) As per claim 25, Walker discloses a central server for examining communicated data from the patient telemetry device (Fig. 1 and col. 4 lines 23-32) comprising:

(i) programs run by the processor (col. 7 lines 12-43) that:

- controlling and communicating with the patient telemetry device regarding the dosage of medication taken by the patient (col. 6 lines 16-33).

Walker fails to expressly disclose ordering medication for a patient from a supplier of medication. Brown discloses obtaining a prescription refill by communicating with the server device (col. 6 lines 1-23 and col. 6 line 55 to col. 8 line 31). At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned component of Brown within the system of Walker with

the motivation of ensuring patient are complying with treatment regimens including having an adequate supply of medication on hand (Brown; col. 1 lines 60-67).

The remainder of claim 25 repeats the same limitations of claims 19, and is therefore rejected for the same reasons given for claim 19, and incorporated herein.

(H) As per claim 27, Brown discloses receiving at the patient device, information about patient compliance with the treatment regimen including medication taken by the patient, physical therapy regimen, psychological therapy, self-help regimen, and tests during a time interval dictated by the treatment regimen (col. 2 lines 1-13, col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 37 to col. 8 line 31). The remainder of claim 27 repeats the same limitations of claim 19, and is therefore rejected for the same reasons given above for claim 19, and incorporated herein. The motivation for combining Brown with Walker is given above in claims 19 and 20, and incorporated herein.

(I) As per claim 28, Brown discloses sending information including the supply and use of pharmaceuticals and medication dosage to the patient device in response to reviewing and evaluating that the patient did not comply with the treatment regimen in the time interval dictated by the treatment regimen (col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 49 to col. 8 line 31). The remainder of claim 28 repeats the same limitations of claim 19, and is therefore rejected for the same reasons given above

for claim 19, and incorporated herein. The motivation for combining Brown with Walker is given above in claims 19 and 20, and incorporated herein.

7. Claims 29, 33-34, 36-37, and 41-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095).

(A) As per claim 29, Walker discloses a method for analyzing data from remote monitoring equipment, such as patient telemetry devices, wherein the disease or physiological parameters relate to at least one of heart rate, high blood pressure, brain waves, ECG data, ventricular fibrillation, loss of consciousness, aberrant blood glucose levels, fetal heart monitor alarm, tachycardia (Fig. 3 and col. 1 lines 10-64), wherein the disease therapy such as for a cardiac patient includes a patient taking a medication and a patient using a patient telemetry device to test and monitor the patient's heart for aberrant data patterns requiring the patient to take a medication (col. 6 lines 16-33 and col. 20 lines 26-55), and wherein an apparatus is able to receive and analyze data from a patient telemetry device (col. 1 line 51 to col. 2 line 27), the method comprising the following steps:

(a) receiving data from a patient, wherein the patient data includes at least one of physiological data or parameter such as heart rate, blood pressure, temperature, perspiration level, respiratory activity, body electrical activity, and brain activity (reads on "neuropsychological data") (Fig. 1, 11-12, col. 3 lines 9-16 and 58-62, and col. 4 lines 60-67);

(b) determining if at least one physiological data or parameter is within appropriate or "normal" parameter boundaries, wherein if the data is not within the appropriate boundary, a central server determines if an event or medical anomaly (e.g. cardiac arrest or other condition) may be occurring, wherein a data profile or template exists for comparing against raw patient data to produce a level of affinity between the profile and data, and wherein a high level of affinity indicates that the data may conform to a medical anomaly or event (Fig. 11-12, col. 1 line 65 to col. 2 line 67, and col. 3 line 55 to col. 4 line 33);

(c) instructing the patient to take insulin if the received results are not within an appropriate boundary, wherein if the blood glucose levels as measured and analyzed by the patient telemetry device, do not return to normal after a predetermined period of time, a physician or nurse is alerted (col. 8 lines 5-40 and col. 20 lines 26-55);

(d) receiving results from a patient at a central server (col. 8 lines 5-40 and col. 20 lines 26-55); and

(e) communicating the physiological representative data including results and levels from the patient telemetry device to an expert, such as a physician or nurse, via the internet, telecommunications network, microwave link, satellite link, wireless communication medium (col. 4 lines 32-49, col. 8 lines 5-40, col. 20 lines 26-55, col. 22 lines 50-67, and col. 26 lines 55-60).

Walker fails to expressly disclose a portable apparatus being configured to receive and analyze information, specifically the information being related to patient compliance with patient-administered medication and test regimens, wherein the

apparatus is configured to modify the patient-administered medication and test regimens.

Brown discloses a method to encourage and monitor compliance with a treatment regimen (col. 3 lines 63-67), wherein a portable device is coupled to a communication system with feedback to monitor patient compliance with and effectiveness of treatment regiments, wherein input from patients regarding treatment regimens can be recorded, reviewed, and analyzed, wherein treatment regimens in response to feedback from patient can be altered by a server device or communication system, wherein the medication regimen includes obtaining medicine, taking medicine, taking medicine with another substance such as food or water, not taking medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill, a physical therapy regimen including exercising, stretching, changing position, or changing work routine, and a psychological regimen including repeating an affirmation, meditation, self-hypnosis or other mental activity, or a self-help regimen such as weight loss including drinking water or eating a snack (Fig. 1-2, col. 1 line 57 to col. 2 line 67, col. 3 lines 1-17, col. 5 lines 3-23, and col. 6 line 55 to col. 8 line 31).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include the aforementioned components of Brown within the method of Walker with the motivation of encouraging and assuring patients comply with the requirements of a treatment regimen (Brown; col. 1 lines 24-60) thus improving the health care provided to patients and allowing patients to be remotely monitored in such a way as to make a preliminary decision about whether a physician should be contacted

(Walker; col. 1 lines 51-63) thus reducing the cost of providing health care services (Brown; col. 2 lines 22-26).

In addition, insofar as Applicant recites "selected from the group consisting of..." and "at least one of...", it is irrelevant whether or not Walker or Brown disclose every single statement recited in the claim.

(B) As per claim 33, Brown discloses receiving from the patient device, information about patient compliance with the treatment regimen including medication taken by the patient, physical therapy regimen, psychological therapy, self-help regimen, and tests during a time interval dictated by the treatment regimen (col. 2 lines 1-13, col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 37 to col. 8 line 31). The motivation for combining Brown with Walker is given above in claim 29, and incorporated herein.

(C) As per claim 34, Walker discloses receiving data from a patient at a central server (col. 8 lines 5-40 and col. 20 lines 26-55) and then transmitting a copy of at least a portion of the patient's medical history and a description of the current pattern or data aberration to the medical expert via a network if at least one physiological data or parameter is not within appropriate or "normal" parameter boundaries (Fig. 11-12, col. 1 line 65 to col. 2 line 67, col. 3 line 55 to col. 4 line 48, col. 5 line 57 to col. 6 line 15, col. 7 lines 12-63).

(D) As per claim 36, Walker and Brown fail to expressly disclose the received patient data including at least one of information about a supra-therapeutic symptom experienced by the patient and information about a sub-therapeutic symptom experienced by the patient. However, Brown discloses sending information to the central server, wherein the information sent is related to compliance with a medication regimen including obtaining medicine, taking the medicine, taking the medicine with another substance such as food or water, not taking the medicine with another substance such as alcohol or incompatible medications, or obtaining a prescription refill (col. 5 lines 8-23 and col. 6 line 55 to col. 8 line 31). It is respectfully submitted that when informing a physician of compliance with a medication regimen, a physician would typically desire to know if a patient had experienced any symptoms, including those associated with an overdose or under dose of the medication regimen. At the time the invention was made, the skilled artisan would have found it an obvious modification to have included information related to symptoms such as overdose or under dose symptoms with the motivation of determining whether treatment regimens are having the desired and intended effects, are effective, or whether patients are suffering any untoward side effects, and monitoring and recording whether non-prescribed treatment regimens, such as by undertaking medication, are producing intended results (Brown; col. 2 lines 1-13).

(E) Claims 37 and 41-42 differ from method claims 29 and 33-34 by reciting hardware elements, namely, a processor, a user interface in communication with the processor,

and computer code executable by the processor. As per these elements, Walker teaches:

(a) a processor (Fig. 1-2 and col. 7 lines 12-43);

(b) a LCD display device including a data entry device to receive and transmit information in communication with a processor (Fig. 1-2 and col. 5 lines 25-44); and

(c) programs run by the processor (col. 7 lines 12-43).

The remainder of apparatus claims 37 and 41-42 repeat the same limitations of method claims 29 and 33-34, and are therefore rejected for the same reasons given above for claims 29 and 33-34, and incorporated herein.

8. Claims 30-32, 35, 38-40, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (6,302,844) in view of Brown (6,161,095) as applied to claims 29 and 37, and further in view of Worthington et al. (6,379,301).

(A) As per claim 30, the relevant teachings of Walker and Brown, and the motivation for their combination is as discussed in the rejections above, and incorporated herein.

Brown discloses modifying the treatment regimen used by a patient and sends the treatment regiment to the patient device using a communication network (col. 7 lines 49-62). However, Walker and Brown fail to expressly disclose the steps of assessing severity of the received test results from the patient-administered test via the portable apparatus, and modifying the patient-administered medication regimen via the portable

apparatus if the received test results from the patient administered coagulation test are assessed to be above a threshold severity level.

Worthington includes a patient-operated apparatus for measuring a blood sample of the patient, and for producing from a measurement of the blood a value, wherein a target range is determined, and wherein if the blood value falls outside of the range when performing the test, corrective action is determined by the processor of the apparatus, and the corrective action is recommended to the patient via the apparatus (col. 4 lines 1-60).

At the time the invention was made, it would have been obvious to one of ordinary skill in the art to include the aforementioned components of Worthington within the method taught collectively by Walker and Brown with the motivation of allowing a patient to make a timely correction when blood tests lie outside of a range (Worthington; col. 3 lines 54-64).

(B) As per claims 31-32, Worthington discloses a healthcare provider computer in communication with the apparatus for receiving from the apparatus values and corrective actions (col. 4 lines 48-60). The remainder of claims 31-32 repeats the same limitations of claim 30, and are therefore rejected for the same reasons given above for claim 30, and incorporated herein. The motivation for combining Worthington within Walker and Brown is given above in claim 30, and incorporated herein.

(D) As per claim 35, Brown discloses sending information including the supply and use of pharmaceuticals and medication dosage to the patient device in response to reviewing and evaluating that the patient did not comply with the treatment regimen in the time interval dictated by the treatment regimen (col. 5 lines 8-23, col. 5 line 48 to col. 6 line 14, and col. 7 line 49 to col. 8 line 31). The remainder of claim 35 repeats the same limitations of claim 30, and is therefore rejected for the same reasons given above for claim 30, and incorporated herein.

(E) Claims 38-40 and 43 repeat the same limitations as claims 30-32 and 35, discussed above, and are therefore rejected for the same reasons given above for claims 30-32 and 35, and incorporated herein.

Conclusion

9. Applicant's amendment filed 30 December 2002 necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Bleck whose telephone number is (703) 305-3981. The Examiner can normally be reached on Monday-Thursday, 8:00am – 5:30pm, and from 8:30am – 5:00pm on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached at (703) 305-9588.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist whose telephone number is (703) 306-1113.

11. **Any response to this action should be mailed to:**

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Or faxed to:

(703) 305-7687 [Official communications; including After Final communications labeled "Box AF"]

(703) 746-8374 [Informal/ Draft communications, labeled "PROPOSED" or "DRAFT"]

Hand-delivered responses should be brought to Crystal Park 5, 2451 Crystal Drive, Arlington, VA, 7th Floor (Receptionist).

CB
October 1, 2003

JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600